



# UNITED STATES PATENT AND TRADEMARK OFFICE

*cl*

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,840	09/23/2003	Paul Alfred Dickinson	CARP-0108	4976

23377 7590 08/07/2006

WOODCOCK WASHBURN LLP  
ONE LIBERTY PLACE, 46TH FLOOR  
1650 MARKET STREET  
PHILADELPHIA, PA 19103

EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
----------	--------------

1616

DATE MAILED: 08/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/668,840	DICKINSON ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 May 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 36- 65 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36- 65 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date: _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date: _____  | 6) <input type="checkbox"/> Other: _____                                    |

Art Unit: 1616

### **DETAILED ACTION**

Receipt of Request for Continued Examination and Affidavit 5/8/06 received on October 24, 2005 is acknowledged. Claims **36- 65** are pending in this application.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/8/06 has been entered.

#### ***Claim Rejections - 35 USC § 102***

The rejection of claims 36-65 under 35 U.S.C. 102(b) as being anticipated by US patent 5,725,841 to Duan et al is withdrawn in view of the amendments of 5/8/06. Duan only teaches a dispersing aid that is derived from an amino acid (amino acid derivative); thus the amendment deleting "amino acid derivative" overcomes the rejection.

The rejection of claims 36-37, 39-48, 50-52, 55-63, and 65 under 35 U.S.C. 102(e) as being anticipated by US patent 6,655,379 to Clark et al is withdrawn in view of the Rule 131 affidavit filed 5/8/06 demonstrating that applicant has possession of the invention prior to Clark et al.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1616

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 36-37, 39-48, 50-52, 54-63, 65 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 90/09781 to Felt.**

Felt discloses a therapeutic aerosol formulation a drug, water-soluble propellant, and an extender. See abstract. The composition is used for inhalation treatment wherein the medication is directly deposited into the airway by nasal or oral route. See page 1. The instant drugs are disclosed on page 6-7 including instant albuterol, instant epinephrine, etc. Specifically, Felt discloses a therapeutic aerosol formulation comprising 0.037% of a drug, 0.152% of L-alanine, ethanol, and a propellant. Example 5. The composition is prepared by combining the components and placing it in a metered aerosol container.

Note MPEP 2111.03 with regard to the claims language. The transitional phrase “consisting essentially of” in independent claims 36, 46, 50, 51, 61, 65 limits the scope of a claim to the specified materials or steps “and those that do not materially affect the basic and novel characteristic(s)” of the claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) “A consisting essentially of” claim occupies a middle ground between closed claims that are written in a consisting of’ format and fully open claims that are drafted in a comprising’ format.” PPG Industries v. Guardian Industries, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir.1998). For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, “consisting essentially of” will be construed as equivalent to “comprising.” See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355. If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of “consisting

Art Unit: 1616

essentially of,” applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant’s invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). In instant case, applicant has the burden of demonstrating the prior art’s a solvent (ethanol) and surfactant (oleic acid) affect the basic and novel characteristics of the composition.

The transitional term “including” in claim 45 and 60 is synonymous with “comprising” and it is inclusive or open-ended and does not exclude additional, unrecited elements or method steps.

***Claim Rejections - 35 USC § 103.***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 38, 49, 53, and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 90/09781 to Felt in view of Barnes et al (5894964).**

Art Unit: 1616

The teachings of Felt have been set forth above. Particularly, Felt teaches dichlorodifluoromethane and trichlorofluoromethane on page 6.

Felt does not teach the instant propellant.

Barnes teaches an aerosol composition. Barnes teaches suitable propellants known in the art include dimethylether, pentane, difluorochloromethane, instant tetrafluoroethane, trichlorofluoromethane, trichlorofluoroethane, difluoroethane, propane, isopentane, isobutane or butane, used singly or in combination.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Felt and Barnes and utilize the instant propellant. One would have been motivated to do so with the expectation of similar results since Barnes teaches Felt's trichlorofluoromethane and the instantly claimed tetrafluoroethane are routinely used in the art and function as propellant in aerosol compositions. Thus, a skilled artisan would have been motivated to substitute the prior art's propellant with the instantly claimed propellant since Barnes teaches both are functionally equivalent, i.e. both are used as propellants.

### ***Conclusion***

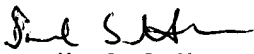
Claims 36-65 are rejected.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1616

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Sharmila S. Gollamudi  
Examiner  
Art Unit 1616

  
JOHANN RICHTER  
SUPERVISORY PATENT EXAMINER  
GROUP 1600

  
Bruce M. Kistlik, Director  
Technology Center 1600